

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS PO Box 1450 Alexascins, Virginia 22313-1450 www.emplo.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/756,890	01/13/2004	H. Phillip Koeffler	066783-0144	3623	
41552 7590 08/19/2008 MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700			EXAM	EXAMINER	
			HUGHES, ALICIA R		
SAN DIEGO,	O, CA 92122		ART UNIT	PAPER NUMBER	
		1614			
			MAIL DATE	DELIVERY MODE	
			05/19/2008	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief

	Application No.	Applicant(s)	
	10/756,890	KOEFFLER ET AL.	
Examiner		Art Unit	
	ALICIA R. HUGHES	1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 March 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

- 1. X The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
 - a) The period for reply expires 6 months from the mailing date of the final rejection.
 - The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
 - Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL

2. The Notice of Appeal was filed on 20 March 2008. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

- **AMENDMENTS** 3. X The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

 - (a) ☑ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☑ They raise the issue of new matter (see NOTE below); (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for
 - appeal; and/or
 - (d) They present additional claims without canceling a corresponding number of finally rejected claims.
- NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
- The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
- Applicant's reply has overcome the following rejection(s): 6. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the
- non-allowable claim(s). 7. X For purposes of appeal, the proposed amendment(s): a) X will not be entered, or b) will be entered and an explanation of
 - how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows:
 - Claim(s) allowed:
 - Claim(s) objected to:
 - Claim(s) rejected: 67.69.70.74.76.78.80.81.83.85.87.95-97.101.103.105.107.108.110.112 and 114.
 - Claim(s) withdrawn from consideration: 61-66.68,71-73.75,77,79.82,84,86.88-94,98-100,102,104,106,109,111,113 and 1.

AFFIDAVIT OR OTHER EVIDENCE

- 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
- 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
- 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.
- REQUEST FOR RECONSIDERATION/OTHER
- 11. X The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
- 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s).
- 13. Other: A review of the specification does not reveal the teaching of a synergistic effect when combining the agents of the claimed invention for the use intended. As such, the effect of amending the claims to include a limitation for synergism is effectively new matter.

/Raymond J Henley III/ Primary Examiner, Art Unit 1614

Application No.

Continuation of 11, does NOT place the application in condition for allowance because: While Applicants ague that the Office has failed to set out a prima facie case of obviousness over any of their examined claims, because Blanchard et al, the central reference in the rejections, do not teach or suggest the method claimed, but at best, describes the use of vitamin D2 compounds for reducing, preventing or treating hair loss (alopecia) induced by a chemotherapeutic agent, and that Blanchards's deficiencies are not cured by the teachings of either ElGendi or Sung et al, most notably because Sung et al describes a solidifiable drug-containing biological material and huge laundy list of numerous exemplany drugs suitable for inclusion in the material, including analgesics, antibiotics, antidepressants, etc., it is known in the art that anti-cancer and chemotherapeutic agents reduce the severity of proliferative disorders associated with care. Further, it is known in the art that paricalcitol is an effective treatment for tissues that contain cancerous cells and/or tumors. As a result, when used together, it would be obvious to one of ordinary skill in the art that the proliferation of cancers and their associated winton sould be diminished. In light of the foregoing, it would have been prima facie obvious to one of ordinary skill in the art to combine paricalcitol with PS341, dexamethasone, daunomycin, arsenic trioxide, taxol, or methortexate to reduce the severity for proliferative disorders.